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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,568	02/01/2002	Phong D. Doan	A00P1012US01	3447
36802	7590	12/21/2004	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER

3762

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,568

Applicant(s)

DOAN ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 7, 8, 11 and 12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 6, 10 and 13-15 is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 3, 4, 7, 8, 11, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected embodiments, there being no allowable generic or linking claim. Election was made **without** traverse by telephone on 9/21/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Littleford (4401127). For claims 1 and 5, Littleford provides for manipulation of the identifier (59 and 60) after the lead is advanced since the lead needs to be adjusted so the identifier has the letters “UP” facing up when it is in the right atrium/ventricle and/or based on the intended site before the advancement of the lead since the identifiers are manipulated and made with the markings based on the intended site in the right atrium/ventricle. Also, although the letters U and P are on the catheter, the letters meet the functional use recitation of referring to one of a right/left atrium/ventricle since the person using the catheter is responsible for identifying the indicia and since the letters UP are made to be seen when the catheter is in the proper position in the right atrium/ventricle. In addition, for claim 9, the identifier is a location related indicia since it has the word “UP” on it and/or since it is related to the position of the electrode in the right atrium/ventricle. Finally, Littleford meets the broad recitation of the word “implantable” since

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the catheter of Littleford is inserted into the body, set deeply in the body, or inserted surgically.

(In addition, see the alternative 103 rejection below).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Littleford in view of Thompson et al (5489275). Littleford discloses the claimed invention using identifiers to indicate when the lead is properly located in the right atrium or ventricle except for the identifier written in specific letters referring to at least one site in the RA, RV, LV, or LA. Thompson teaches that it is known to include on cardiac catheters identifiers to indicate the RA or RV to make it easier to identify the particular site of the catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac system and method of inserting a cardiac lead in the body as taught by Littleford, with

identifiers to indicate the RA or RV since it will provide a cardiac system and method of inserting a cardiac lead in the body with identifiers to indicate the RA or RV to make it easier to identify the particular site of the catheter.

Allowable Subject Matter

Claims 2, 6, 10, and 13-15 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The argument that Littleford's identifiers do not refer to at least one of a right/left atrium/ventricle is not persuasive since it is dependent on the user of the device to interpret the identifier. Just as the applicant uses RA or RV to identify the right atrium or right ventricle, the user of the applicant's invention must interpret RA or RV to know that the catheter is located in one of those sites. Someone who does not speak English will need to be told what RA and RV mean, just as someone who uses Littleford's device can be told that UP means the right atrium or right ventricle. Although the letters U and P are on the device, they are still an identifier of at least one site in the heart. In addition, when the lead is implanted correctly, the letters UP will be seen to identify the correct location of the lead in the right atrium or right ventricle.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
December 15, 2004


GEORGE R. EVANISKO
PRIMARY EXAMINER

12/15/04